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Europäisches Patentamt  
European Patent Office  
Office européen des brevets



(11)

EP 0 948 970 A2

(12)

## EUROPEAN PATENT APPLICATION

(43) Date of publication:  
13.10.1999 Bulletin 1999/41

(51) Int. Cl.<sup>6</sup>: A61M 25/06

(21) Application number: 99114016.1

(22) Date of filing: 06.07.1992

Lee  
Gane

(84) Designated Contracting States:  
AT BE CH DE DK ES FR GB GR IT LI LU MC NL  
PT SE

(30) Priority: 09.07.1991 US 727191  
26.06.1992 US 905045

(62) Document number(s) of the earlier application(s) in  
accordance with Art. 76 EPC:  
92919181.5 / 0 593 685

(71) Applicant:  
H.L. MEDICAL INVENTIONS, INC.  
Rancho Palos Verdes, CA 90274 (US)

(72) Inventor: Lee, Hongpyo H.  
Rancho Palos Verdes, CA 90274 (US)

(74) Representative: Hager, Thomas J.  
Hoefer - Schmitz - Weber  
Patentanwälte  
Gabriel-Max-Strasse 29  
D-81545 München (DE)

### Remarks:

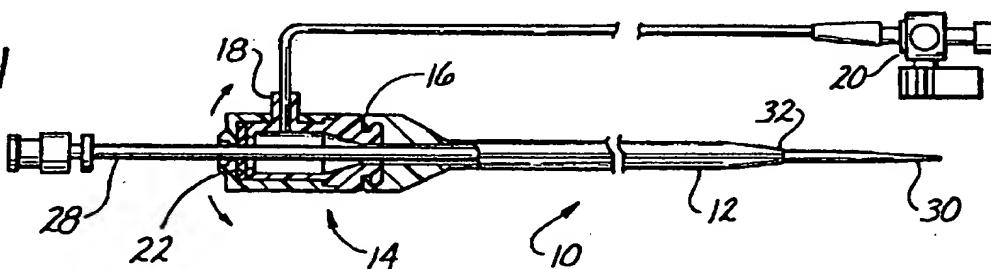
This application was filed on 19 - 07 - 1999 as a  
divisional application to the application mentioned  
under INID code 62.

### (54) Splittable sheath assembly

(57) The invention relates to an apparatus for use  
for vascular implantation of a lead or catheter comprising  
a separable introducer sheath (12) adapted for dis-  
position within a body lumen; a separable hemostatic  
valve (14) coupled to said introducer sheath (12), said  
hemostatic valve (14) for sealing said lead or catheter  
within said hemostatic valve (14) to prevent bleeding or  
introduction of air into said body lumen when said lead  
or catheter is introduced into said body lumen; char-  
acterized in that the apparatus comprises means for per-

mitting removal of said separable introducer sheath (12)  
and said separable hemostatic valve (14) from said lead  
or catheter without sliding either said separable intro-  
ducer sheath (12) or said separable hemostatic valve  
(14) over said lead or catheter; and means for separat-  
ing said separable introducer sheath (12) and said sep-  
arable hemostatic valve (14) in a controlled and  
predictable manner to permit removal from said lead or  
catheter.

Fig. 1



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## Description

[0001] The invention relates to the field of pacemaker leads and catheters and in particular to leads used in veins such as in connection with pacemaker procedures such as pacemaker lead insertion.

[0002] There are many medical procedures which require a puncture and catheterization of an artery or vein for various purposes.

[0003] In the prior art process of percutaneous puncture, a guidewire is introduced into the vessel through a hollow needle. The needle is withdrawn leaving the guidewire in the vessel. A TEFILON dilator and venous sheath assembly are then advanced in a rotary motion over the guidewire into the vessel. The TEFILON dilator and the guidewire are then removed leaving the flexible sheath in the vessel. At this point, various types of catheters or leads are inserted using the sheath as a conduit to avoid tearing or further trauma to the vessel wall.

[0004] In the case where a pacemaker lead must be permanently inserted into the patient, the pacemaker is subcutaneously implanted in the patient and the lead, which extends from the pacemaker into the heart chamber, remains permanently disposed through the vessel wall and in the vessel lumen. A sheath is nevertheless used in order to guide insertion of the lead into vein lumen, but must be removed leaving the lead in place. However, the sheath cannot simply, in all cases, be slipped over the exterior end of the pacemaker lead which may be provided with a special termination for connection to the pace-maker.

[0005] In this case, the prior art has devised a number of splittable or peel away sheaths. The sheath is scored so that it is withdrawn by splitting or peeling it off from the pacemaker catheter. See Philip O. Littleford, et al, "The American Journal of Cardiology," Vol. 43, pp. 980-982 (May 1979); Littleford, "Apparatus and Method for Inserting an Electrode," U.S. Patent 4,166,469 (1979); Littleford, "Method for Inserting Pacemaker Electrodes and the Like," U.S. Patent 4,243,050 (1981) and Littleford, "Split Sleeve Introducers for Pacemaker Electrodes and the Like", U.S. Patent 4,345,606 (1982); Osborne, "Tear Apart Cannula," U.S. Patent Reissue 31,855 (1985), a reissue of U.S. Patent 4,306,562 (1981); Boarini et al., "Peelable Catheter with Securing Ring and Suture Sleeve," U.S. Patent 4,411,654 (1983); Moorehead, "Medical Layered Peel Away Sheath and Methods," U.S. Patent 4,983,168 (1991). A splittable cannula is also taught by Kousai et al., "Medical Tool Introduction Cannula 15 and Method of Manufacturing the Same," U.S. Patent 4,883,468 (1989).

[0006] However, in each of these prior art sheath assemblies, once the sheath has been inserted the sheath provides a passage for the free flow of blood. In practice a significant amount of bleeding may occur at the operation site, which requires constant mopping and cleaning. The amount of loss of blood during an operation may begin to have a negative impact upon the

patient.

[0007] Secondly, in addition to the sheath assembly providing an open passage for the loss of blood, the sheath assembly also provides an open passage for the introduction of air into the vein. The inadvertent introduction of air into the blood system causes air embolism in the patient and its consequent negative effects.

[0008] Thirdly, clotting may be formed in the lumen of the sheath if the sheath remains in for a prolonged time, and this may cause embolism to the lung and its consequent negative effects.

[0009] Because of the three problems above, the prior art splittable sheath has to be removed as soon as the lead is introduced into the vessel lumen, although it is very desirable to retain the sheath in place throughout operation because the lead can be manipulated much easier without interference from other existing lead or tissue friction and can be exchanged freely without repeated sheath insertion trauma.

[0010] When the catheter or lead is introduced in the sheath, a certain amount of blood leakage will occur between the catheter and the sheath walls. The prior art has also devised hemostatic valves which provide a seal around the catheter introduced through the sheath.

[0011] One such sheath and hemostatic valve is manufactured and marketed by Cordis Corp. of Miami, Florida as the UNISTASIS valve in the Cordis catheter sheath introducer. Another example is manufactured by Bard of Billerica, Massachusetts as the 5F HEMAQUET introducer.

[0012] A hemostatic valve combined with a splittable sheath is also illustrated in Schiff, "Introducer Assembly for Intra-Aortic Balloons and the Like Incorporating a Sliding, Blood-Tight Seal," U.S. Patent 4,473,067 (1984).

[0013] However, all the prior art hemostatic valve structures, even when combined with a splittable sheath, such as shown by Schiff, are integral or rigid units, which do not split and must be removed by sliding along the end of the catheter. In the case of Schiff, the sheath is split in order to appropriately position the balloon catheter. However, after the balloon angioplasty procedure is completed, the entire catheter is removed so that at no point is the hemostatic valve entirely removed from the catheter nor need it be.

[0014] What is needed then is some type of sheath and valve system which can be used in connection with our vessel introducers, which introducers can then remain in place without risking undue bleeding, air embolism, or clotting while retaining the advantages of an introducer sheath for free lead exchange and easier lead manipulation.

[0015] Moreover, DE 37 21 288 C1 describes only a sealing packing for a catheter introducer. Again in this document the catheter introducer and the sealing packing are constituted of two separate components which are each formed of two separate halves. Thus, neither the introducer nor the sealing packing of DE 37 21 288 C1 are made of one piece but of two pieces.

[0016] Furthermore, DE 38 34 600 C1 describes an

apparatus for use for vascular implantation of a lead or catheter having a sheath and valve assembly. However, the sheath and valve assembly are constructed of two separate components which can not come apart from a catheter as a single unit.

[0015] EP 0 226 397 A2 describes a disposable catheter insertion apparatus according to the over-the-needle technology. The introducer for a catheter comprises a tubular shield consisting of two parts which are snapped together. The tubular shield has a distal arm extending axially thereof to which is attached a tube extending proximally into the shield and spaced from the wall thereof. The tube is to receive a catheter and the inner annular space between the tube and the shield receives a protective sheath for the catheter. On insertion of the catheter the sheath emerges through a side opening in the introducer.

[0016] It is an object of the present invention to provide a sheath and valve system which can be used in connection with vessel introducers, which introducers can then remain in place without risking undue bleeding, air embolism, clotting while retaining the advantages of a introducer sheath for free lead exchange and easier lead manipulation.

[0017] According to the invention, the object is solved by the combination of features of claim 1, 14 and 15, respectively. The sub-claims contain further preferred embodiments of the invention.

[0018] The invention is an apparatus for use for vascular implantation of a lead or catheter comprising: a separable introducer sheath adapted for disposition within a body lumen; a separable hemostatic valve coupled to said introducer sheath, said hemostatic valve for sealing said lead or catheter within said hemostatic valve to prevent bleeding or introduction of air into said body lumen when said lead or catheter is introduced into said body lumen; characterized in that the apparatus comprises means for permitting removal of said separable introducer sheath and said separable hemostatic valve from said lead or catheter without sliding either said separable introducer sheath or said separable hemostatic valve over said lead or catheter; and means for separating said separable introducer sheath and said separable hemostatic valve in a controlled and predictable manner to permit removal from said lead or catheter.

[0019] As a result, the apparatus may safely remain in the vessel lumen throughout the operation without substantial bleeding, risk of air embolism clotting, or need of repeated sheath insertion for lead exchange.

[0020] The element for permitting removal of the hemostatic valve and introducer sheath is a element for splitting the introducer sheath and hemostatic valve away from the lead or catheter which is disposed therethrough.

[0021] Alternatively, the element for permitting removal of the introducer sheath and the hemostatic valve is a element for peeling away the introducer

sheath and hemostatic valve from the lead or catheter therethrough.

[0022] In the illustrated embodiment the element for permitting removal of the hemostatic valve and introducer sheath is a score line defined in the hemostatic valve and introducer sheath along which the hemostatic valve and introducer sheath may be separated. The score line comprises a pair of lines defined in the hemostatic valve and introducer sheath. The pair of score lines are diametrically opposed from each other on the hemostatic valve and introducer sheath. The score line is disposed along the longitudinal length of the hemostatic valve and introducer sheath. The score line defined into the introducer sheath is aligned with the score line deemed into the hemostatic valve.

[0023] The hemostatic valve is self sealing. The hemostatic valve and sheath are arranged and configured to allow the insertion therethrough of multiple leads or catheters. The hemostatic valve further comprises an intravenous sidearm assembly. The element for permitting removal of the hemostatic valve and sheath leaves the sidearm assembly intact.

[0024] The use of the inventive apparatus comprises the steps of disposing an introducer sheath and hemostatic valve coupled to the introducer sheath into a body lumen. At least one lead or catheter is disposed through the valve and introducer sheath into the body lumen. The lead or catheter is sealed within the hemostatic valve to prevent bleeding and introduction of air into the body lumen with disposition of the lead or catheter therein. The hemostatic valve and introducer sheath is removed while leaving the lead or catheter in place within the body lumen without sliding either the introducer sheath or hemostatic valve over an end of the lead or catheter. As a result, implanted leads or catheters may be disposed into the body lumen without bleeding, risk of air embolism, clotting or requiring the end of the lead or catheter to have a structure to permit removal of the sheath and valve thereover.

[0025] The step of removing the sheath and lead or catheter comprises the step of splitting the sheath and valve along a longitudinal length of the sheath and valve and disposing the lead or catheter radially through the longitudinal split.

[0026] More particularly, the step of splitting the sheath and valve comprises a step of splitting the sheath and valve along a score line by manually tearing the sheath and valve apart along the score line.

[0027] The step of tearing the sheath and valve further comprises tearing the sheath and valve along a pair of longitudinally defined score lines in the sheath and valve. The step of tearing the valve and sheath along a pair of score lines comprises in turn the step of tearing the valve and sheath along diametrically opposing longitudinally defined score lines in the valve and sheath respectively.

[0028] The invention is an improvement in an introducer sheath and valve assembly for implantation of

pacemaker leads comprising an element for splitting the introducer sheath. The sheath has a longitudinal axis. The element for splitting allows manual separation of the sheath along the longitudinal axis. An other element for separating the hemostatic valve permits removal of the valve from the lead without necessitating removal of the valve over an end of the lead. As a result, the sheath can remain in place throughout the operation with the advantage of free lead exchange and easier lead manipulation without bleeding, air embolism clotting and repeated sheath related trauma for possible lead exchange.

[0029] The hemostatic valve comprises a resealable membrane. The element for permitting the removal of the hemostatic valve and introducer sheath comprises a cut in the resealable membrane to facilitate parting of the membrane.

[0030] The cut is a Y-shaped cut extending partially through the membrane. The intersection of the Y-shaped cut is positioned approximately near the center of the membrane with one leg of the Y extending toward the periphery of the membrane in a direction along which the membrane will be separated.

[0031] The invention is better visualized by now turning to the following drawings wherein like elements are referenced by like numerals.

Figure 1 is a partially cutaway side view of a splittable introducer sheath devised according to the invention.

Figure 2 is an enlargement of the splittable valve portion shown in Figure 1 wherein a lead or catheter has been disposed through the valve.

Figure 3 is a rear prospective view of the valve and sheath combinations of Figures 1 and 2 showing an embodiment of diametric longitudinal score lines.

Figure 4 is a simplified side elevational view of an additional embodiment of the invention.

Figure 5 is a side cross-sectional view in enlarged scale of selected cutaway portions of the hemostatic valve and sheath of Figure 4.

Figure 6 is a perspective view of the diaphragm of the hemostatic valve of Figure 5 shown in isolation of all remaining elements.

Figure 7a and 7b is a perpendicular cross-sectional view of the valve of Figures 4 and 5

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Figure 8

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Figure 9a

15

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Figure 10

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30 [0032] The invention and its various embodiments may now be understood by turning to the following detailed description.

[0033] An improved hemostatic valve and introducer sheath is provided for introductions of leads or catheters through the valve and sheath combination into a vessel or artery. At the point in the operation where the introducer sheath and 35 hemostatic valve must be removed from the lead or catheter, which must remain implanted, means are employed to split or separate the introducer sheath and valve apart so that the sheath and valve are removed from the implanted lead or catheter without the necessity of sliding either the sheath or valve over the free end of the lead or catheter. The hemostatic valve is made in two separate parts which include a fluidtight seal to facilitate splitting of the valve. In this manner, any termination which may be provided on the free end of the lead or catheter, such as a terminal for connection to a pacemaker, will not interfere with the optimal use of the introducer sheath and hemostatic valve.

50 [0034] A splittable introducer sheath and valve assembly, generally noted by reference numeral 10 in Figure 1, is depicted in partially cutaway side view. Valve and sheath assembly 10 comprise a splittable sheath 12 connected, coupled or extending from a splittable hemostatic valve assembly 14. Valve assembly 14 in turn is comprised of a valve body 16, an intravenous sidearm 18 with a sidearm of valve 20. The details of the design of sidearm valve 20 and to a certain extent side-

as seen through sectional line 7-7 of Figure 5. Figure 7a shows the valve body assembled and closed with tape as shown in Figure 4, while Figure 7b shows the tape removed and valve body halves separated.

shows another embodiment of the valve body in perpendicular cross-sectional view as would be seen through section line 7-7 of Figure 5.

is another embodiment of the valve body wherein a tongue and groove connection and pop-out indentation is provided. Figure 9b is the side elevational of the valve body, the perpendicular cross-sectional of which is shown in Figure 9a as seen through section lines 9a-9a of Figure 9b.

is another embodiment of the valve body as seen in the perpendicular cross-sectional view as would be seen through section line 7-7 of Figure 5.

30 [0032] The invention and its various embodiments may now be understood by turning to the following detailed description.

[0033] An improved hemostatic valve and introducer sheath is provided for introductions of leads or catheters through the valve and sheath combination into a vessel or artery. At the point in the operation where the introducer sheath and 35 hemostatic valve must be removed from the lead or catheter, which must remain implanted, means are employed to split or separate the introducer sheath and valve apart so that the sheath and valve are removed from the implanted lead or catheter without the necessity of sliding either the sheath or valve over the free end of the lead or catheter. The hemostatic valve is made in two separate parts which include a fluidtight seal to facilitate splitting of the valve. In this manner, any termination which may be provided on the free end of the lead or catheter, such as a terminal for connection to a pacemaker, will not interfere with the optimal use of the introducer sheath and hemostatic valve.

50 [0034] A splittable introducer sheath and valve assembly, generally noted by reference numeral 10 in Figure 1, is depicted in partially cutaway side view. Valve and sheath assembly 10 comprise a splittable sheath 12 connected, coupled or extending from a splittable hemostatic valve assembly 14. Valve assembly 14 in turn is comprised of a valve body 16, an intravenous sidearm 18 with a sidearm of valve 20. The details of the design of sidearm valve 20 and to a certain extent side-

arm 18 are largely inconsequential to the present invention and therefore will not be further described except insofar as necessary to illustrate the invention. Hemostatic valve assembly 14 is shown in Figure 1 in cutaway view exposing the interior of valve 16 which includes a valve membrane 22. The details of valve assembly 14 again are not critical to an understanding of the invention, but in the preferred embodiment, valve membrane 22 is a self-healing membrane through which a lead or catheter may be introduced without leakage between membrane 22 and leads or lead 24 such as shown in the partially cutaway view of Figure 2 depicted in expanded scale. Valve body 16 in the illustrated embodiment is comprised of two sections 16a and b which are bonded together after assembly.

[0035] In the depiction of Figure 1, a conventional dilator 28 is shown as disposed through valve assembly 14 and sheath 12 having a tapered tip 30 extending from the distal end 32 of sheath 12. As in the conventional methodology described above in connection with percutaneous sheath lead or catheterization, the artery or vessel is punctured with a needle into which a guidewire is placed. The needle removed and then dilator and sheath assembly 12 advanced on the guidewire into the vessel. The guidewire will extend through valve assembly 14 and be sealed by means of membrane 22. The guidewires and TEFLON dilator are then removed leaving the flexible sheath assembly 10 in place. However virtually no bleeding occurs since the entire assembly is sealed by self-healing membrane 22. At this point one or more leads or catheters as suggested in Figure 2 can be introduced, removed and reintroduced and manipulated without any significant possibility of bleeding, clotting, risk of air embolism or repeated sheath insertion related trauma since once inserted sheath assembly 10 is in place regardless of the number of leads or catheters inserted and removed throughout the operation.

[0036] In addition, since sealing of leads or catheters 24 and 26 is effectuated by membrane 22 of valve assembly 14, valve body 16 and at least a portion of sheath 12 may be made larger than normal to allow a more loose fit between the interior surfaces of introducer sheath assembly 10 and leads or catheters 24 and 26, since blood sealing between the lead or catheter and sheath 12 is not required. This allows leads or catheters 24 and 26 to be introduced and removed from introducer sheath assembly 10 with less friction or interference with assembly 10 and with each other. Therefore the lead can be manipulated much easier.

[0037] The detailed construction of sheath 12 and valve assembly 14 as previously implied is not critical to the invention, at least to the extent of whether sheath 12 and valve assembly 14 must be separate or integral parts or how they may be connected with each other. Therefore, it must be expressly understood that valve assembly 14 and sheath 12 may be fabricated according to any structure or out of any material now known to the art or later devised without departing from the scope

of the invention. For example, sheath 12 may be integrally molded or cast with valve assembly, may be adhesively affixed thereto, may be compression fitted, slip fit, threaded, or connected in any manner desired to valve assembly 14 consistent with the teachings of the present invention.

[0038] Figure 3 illustrates in enlarged scale a rear perspective view of introducer sheath assembly 10. According to the invention, both valve assembly 14 and sheath 12 are splittable or have a peel away construction. Again, the detailed nature by which such splittable structure is implemented or how peel-away feature is realized is not critical to the invention. Any method now known by which such sheaths 12 and valve assemblies 14 may be split or separated may be employed.

[0039] The illustrated embodiment, sheath 12 and valve assembly 14 are shown as integrally fabricated and having a pair of longitudinal score lines 34 and 36 defined along their axial length. Score lines 34 and 36 are shown as being diametrically opposed from each other across the cross section of introducer sheath 10. Intravenous sidearm 18 is depicted in Figure 3 as being disposed between score lines 34 and 36 interlying surface between them. Score lines 34 and 36 are shown as 25 having a V-shaped cross section but have such a shape and depth as to permit the entire length of introducer sheath 10 to be manually separated. It is contemplated that at the end of the operation the physician will grasp opposing flange portions 38 and 40 to peel them apart 30 while pulling out the sheath and holding the lead. This will cause valve body 16 to tear along a section line depicted by dotted lines 42 through the body of valve assembly 14. Both body portions 16a and b may be scored to facilitate this tearing. In addition the bonding 35 of the body portions 16a and 16b assists in tearing the inner body portion as the outer body portion is being torn along its corresponding tear line. The portions become through the bonding as a single body and the fracture or tear propagates from the outer body portion 40 through the inner body portion. Membrane 22 has a weak line or score line and can easily be removed from the lead.

[0040] In the illustrated embodiment flanges 38 and 40 are formed in two halves having diametrically opposing slots 44 and 46 aligned with score lines 34 and 36 defined into valve body 16. However, it is entirely possible that score lines 34 and 36 will be continued through flanges 38 and 40 to provide deep scores instead of open slots 44 and 46.

[0041] In any case, valve body 16 is peeled apart with separation continuing through any transition portion 48 between valve body 16 and sheath 12 and on along the longitudinal length of sheath 12. Sheath 12 is then removed and peeled followed by additional removal of sheath 12 from the puncture site and peeling of the removed portions until the entire valve and introducer sheath assembly 10 of Figure 1 has been split and removed from the lead or catheter, which is then perma-

nently implanted into the puncture site and with which the surrounding tissue makes a blood tight seal.

[0042] The hemostatic valve and sheath 10 as seen in Figure 1 is shown in an alternative embodiment and side elevational view in Figure 4. In the embodiment of Figure 4, splittable hemostatic valve assembly 14 is integrally molded or made separable from splittable sheath 12 and fitted at its proximal end with a dilator head fitting 50. Dilator head fitting 50 as shown in enlarged view in Figure 5 is secured to valve assembly 14 by means of a conventional Luer lock 52. The score line 34 on sheath 12 continues along sheath 12 into split body portion 14a and 14b which comprise the body of valve assembly 14. Valve membrane 22, disposed within valve assembly 14, is also provided with a Y-shaped incision 54 as best depicted in the perspective view of Figure 6 to facilitate opening and tearing of membrane 22 when valve body halves 14a and 14b are separated.

[0043] In the embodiment of Figure 4, valve halves 14a and 14b are temporarily fixed together by means of tearable single-sided adhesive tape 56. The binding of the body portions and the hemostatic membrane need not be excessively sturdy since the device is used at low pressures, 5-10 mm Hg and its use is typically of only 10-30 minutes duration. The long leg of the Y shape incision into or through membrane 22 may or may not extend to the periphery of membrane 22 as may be needed to facilitate its tearing or cutting.

[0044] The practicing physician may then take a scalpel and easily cut tape 56 along the split line 34 and valve assembly 14 thereby separating the valve body portions 14a and 14b. As described above with the body portions 14a and 14b separated, sheath 12, which is integral, is then readily split along score line 34.

[0045] Valve body 14 may be manufactured from valve body portions 14a and 14b in a number of alternative forms. One embodiment is shown in Figure 7a and 7b wherein valve body 14 is generally split into two halves, an upper half 14b and a lower the half 14a. Lower half 14a is provided with an interior circumferential lip 58a which slip fits into an exterior circumferential lip 58b defined in upper body half 14b. The two body halves, 14a and 14b, as shown in Figure 7, which is a perpendicular cross-sectional view taken through section lines 7-7 of Figure 5, are then held together us tape 56. Once the tape is cut, the two body halves may then be manually separated as depicted in Figure 7b. While assembled, however, valve assembly 14 provides a water-tight or blood-tight valve assembly.

[0046] Another embodiment of the body of valve assembly 14 is depicted in the perpendicular cross-sectional view of Figure 8 as would also be seen through section line 7-7 of Figure 5. In the embodiment of Figure 8, lower body portion 14a comprises a rectangular box, while upper body portion 14b is formed like a lid covering and seals the box-shape of body portion 14a. In the embodiment of Figure 8, the outer circumferential seal

60a is provided on the lower body portion 14a while the inner circumferential seal 60b is defined on the upper lid body portion 14b, which is the conceptional reverse of the embodiment of Figure 7.

[0047] Figures 9a and 9b illustrate yet another embodiment in which lower body portion 14a again defines a box-like shape and is coupled to upper body portion 14b acting as a lid, the two portions comprising an interior tongue and groove snap-fit seal. In the embodiment of Figure 9a, which is a perpendicular cross-sectional view as would be seen through section lines 7-7 of Figure 5, a groove 62a is defined in lower body portion 14a while a mating tongue 62b is provided in upper lip portion 14b. Along the side of valve assembly 14 is a cut-out recess 64 in a least one position along line 34 wherein the surgeon can insert a scalpel or tool to pry body portions 14a and 14b apart. Thus, it is contemplated that at least in the embodiment of Figures 9a and 9b, if not other ones of the embodiment shown, that the need for tape 56 may be unnecessary in that the body portions will fit tightly together by virtue of their snap fit. The disengagement will then be affected by Prying them apart, with the assistance, if necessary, of a recess 64 as depicted in Figures 9a and 9b.

[0048] Yet another embodiment of valve body 14 is depicted in perpendicular cross-sectional view of Figure 10, again as would be seen through section line 7-7 of Figure 5. In the embodiment of Figure 10, separation between body portions 14a and 14b occurs generally along the mid-portion of lateral sides 66 of valve body 14 and are defined by providing a knife edge seal 68 in the one body portion, such as lower body portion 14a, and a conforming groove 70 in the opposing body portion, such upper portion 14b. Again, portions 14a and 14b may be held together by an exterior tape 56 or may have a snap-fit facilitated by an expanded head 72 below knife edge 78 which is accommodated by a snap-fit conforming interior shape of groove 70.

[0049] It must be understood that many other embodiments may be devised by which the body portion of valve assembly 14 may be manufactured as separate halves and then be temporarily joined together with or without the aid of an exterior fastening means such as tape, friable spots of adhesive disposed in the joints between body portions 14a and 14b, or various compression fitting seals, some of which have been depicted by way of illustration in Figures 7-10.

## Claims

50 1. An apparatus for use for vascular implantation of a lead or catheter comprising:

55 a separable introducer sheath (12) adapted for disposition within a body lumen;

a separable hemostatic valve (14) coupled to said introducer sheath (12), said hemostatic

valve (14) for sealing said lead or catheter within said hemostatic valve (14) to prevent bleeding or introduction of air into said body lumen when said lead or catheter is introduced into said body lumen;

CHARACTERIZED in that the apparatus comprises

means for permitting removal of said separable introducer sheath (12) and said separable hemostatic valve (14) from said lead or catheter without sliding either said separable introducer sheath (12) or said separable hemostatic valve (14) over said lead or catheter; and

means for separating said separable introducer sheath (12) and said separable hemostatic valve (14) in a controlled and predictable manner to permit removal from said lead or catheter.

2. The apparatus of claim 1 where said means for separating said separable introducer sheath (12) and said separable hemostatic valve (14) in a controlled and predictable manner comprises a compression seal (Fig. 7b, 56, 58a, 58b, 62a, 62b, 60a, 60b, 70, 72) between separable portions (14a, 14b) of said separable hemostatic valve (14).
3. The apparatus of claim 2 wherein said compression seal (Fig. 7b, 56, 58a, 58b, 62a, 62b, 60a, 60b, 70, 72) between separable portions (14a, 14b) of said separable hemostatic valve (14) comprises adhesive tape (56) wound around valves halves (14a, 14b).
4. The apparatus of claim 2 wherein said temporary compression seal (Fig. 7b, 56, 58a, 58b, 62a, 62b, 60a, 60b, 70, 72) between separable portions (14a, 14b) of said separable hemostatic valve (14) comprises slip fit valves halves (14a, 14b).
5. The apparatus of claim 2 wherein said temporary compression seal (Fig. 7b, 56, 58a, 58b, 62a, 62b, 60a, 60b, 70, 72) between separable portions (14a, 14b) of said separable hemostatic valve (14) comprises valves halves (14a, 14b) which are slip-fit together.
6. The apparatus of claim 5 wherein said slip fit valves halves (14a, 14b) comprise a lid (14b) and a base (14a) and wherein said compression seal is formed between said lid (14b) and base (14a) by contact under pressure between mating peripheral portions of said lid (14b) and base (14a).
7. The apparatus of claim 6 wherein said compression seal formed between said lid (14b) and base (14a)

5 by contact under pressure between mating peripheral portions of said lid (14b) and base (14a) is formed between an inner lip (58a) of said base (14a) and an outer lip (58b) of said lid (14b).

8. The apparatus of claim 6 wherein said compression seal formed between said lid (14b) and base (14a) by contact under pressure between mating peripheral portions of said lid (14b) and base (14a) is formed between an inner lip (60b) of said lid (14b) and an outer lip (60a) of said base (14a).
9. The apparatus of claim 6 wherein said compression seal formed between said lid (14b) and base (14a) by contact under pressure between mating peripheral portions of said lid (14b) and base (14a) is formed between a tongue (62b) and an groove (62a) formed in said mating peripheral portions.
10. The apparatus of claim 9 wherein said tongue (62b) is formed in said lid (14b) and said groove (62a) is formed in said base (14a).
11. The apparatus of claim 9 wherein said tongue (62b) is formed in said base (14a) and said groove (62a) is formed in said lid (14b).
12. The apparatus of claim 9 wherein said tongue (72) is snap fit into said groove (70).
13. The apparatus of claim 2 wherein said compression seal (Fig. 7b, 56, 58a, 58b, 62a, 62b, 60a, 60b, 70, 72) between separable portions (14a, 14b) of said separable hemostatic valve (14) employs a resilient force to temporarily maintain said separable portions (14a, 14b) of said separable hemostatic valve (14) in contact with each other.
14. An apparatus for use for vascular implantation of a lead or catheter comprising:
  - 40 a separable introducer sheath (12) adapted for disposition within a body lumen;
  - 45 a separable hemostatic valve (14) coupled to said introducer sheath (12), said hemostatic valve (14) for sealing said lead or catheter within said hemostatic valve (14) to prevent bleeding or introduction of air into said body lumen when said lead or catheter is introduced into said body lumen;
  - 50 CHARACTERIZED in that the apparatus comprises
  - 55 means for permitting removal of said separate introducer sheath (12) and said separate hemostatic valve (14) from said lead or catheter without sliding either said separate intro-

ducer sheath (12) or said separate hemostatic valve (14) over said lead or catheter comprises two portions (14a, 14b) of said separate hemostatic valve (14), which are temporarily in contact with each other under force to provide a seal and then are at least in part separated from each other to permit removal of said two portions (14a, 14b) of said separate hemostatic valve (14) from said lead or catheter; and

means for separating said separate introducer sheath (12) and said separate hemostatic valve (14) in a controlled and predictable manner to permit removal from said lead or catheter.

15. A sheath assembly for use with a lead or catheter comprising:

an introducer sheath;

a hemostatic valve coupled to said introducer sheath, said hemostatic valve and introducer sheath being arranged and configured to permit introduction of at least one lead or catheter therethrough;

means for permitting removal of said hemostatic valve and introducer sheath from said lead or catheter disposed therethrough without requiring said introducer sheath and hemostatic valve to be removed from an end of said lead or catheter,

wherein said means for permitting removal of said hemostatic valve comprises a two-part body, said two-part body being made in two separate body portions, said body portions including means for forcing said body portions together so that said two body parts are maintained in contact with each other to form said hemostatic valve and to provide temporary sealing about said lead or catheter,

whereby said assembly may remain in a vein throughout an operation with the advantage of free lead exchange and easier lead manipulation without substantial bleeding, risk of air embolism, clotting or repeated sheath insertion causing related trauma from lead exchange,

16. The sheath assembly of claim 15 wherein said hemostatic valve further comprises a resealable or compression membrane and wherein said means for permitting the removal of said hemostatic valve comprises a cut in said resealable membrane to facilitate parting of said membrane wherein said body portions are pulled apart.

17. The sheath assembly of claim 16 wherein said cut is a Y-shaped cut extending at least partially

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through said membrane, the intersection of said Y-shaped cut being positioned approximately near the center of the said membrane with one leg of said Y extending toward the periphery of said membrane in a direction along which said membrane will be separated when said portions are parted.

18. The sheath assembly of claim 15 wherein said means for sealing said body portions together comprise a circumferential sealing periphery on each of said body portions said sealing periphery on one body portion being forced into contact with said sealing periphery on said other body portion to make said hemostatic valve fluid-tight wherein said body portions are temporarily forced together.

19. The sheath assembly of claim 15 further comprising a sidearm disposed in said hemostatic valve downstream from said valve which is used to continuously flush said introducer sheath to prevent coagulation in said introducer sheath.

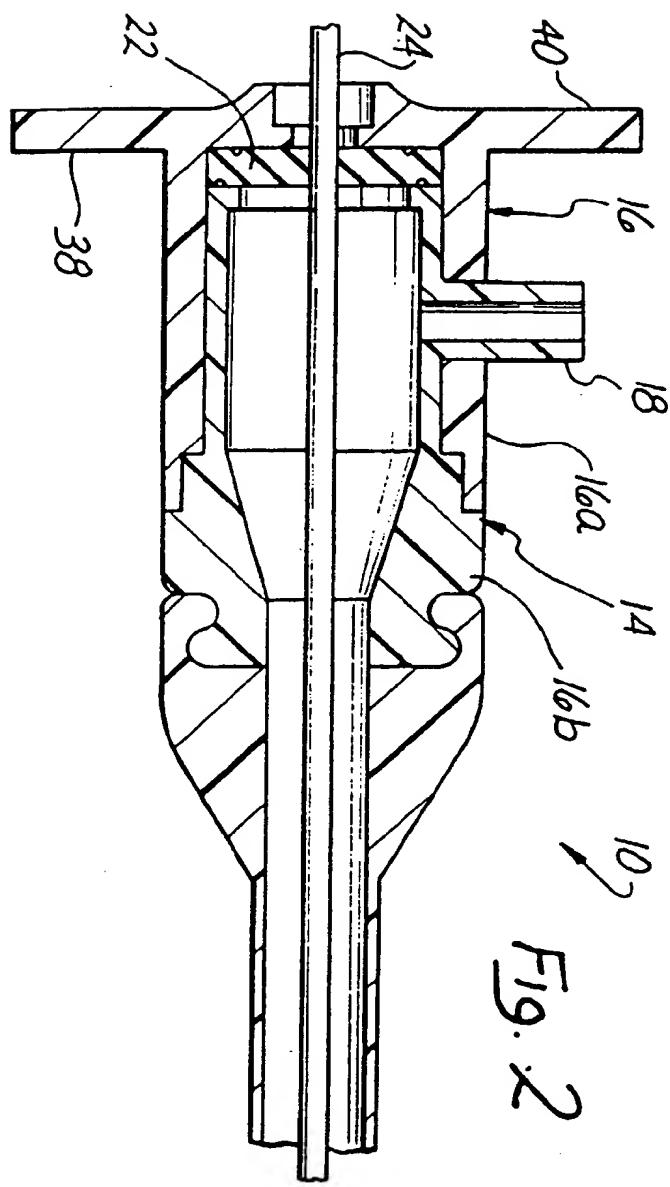


Fig. 2

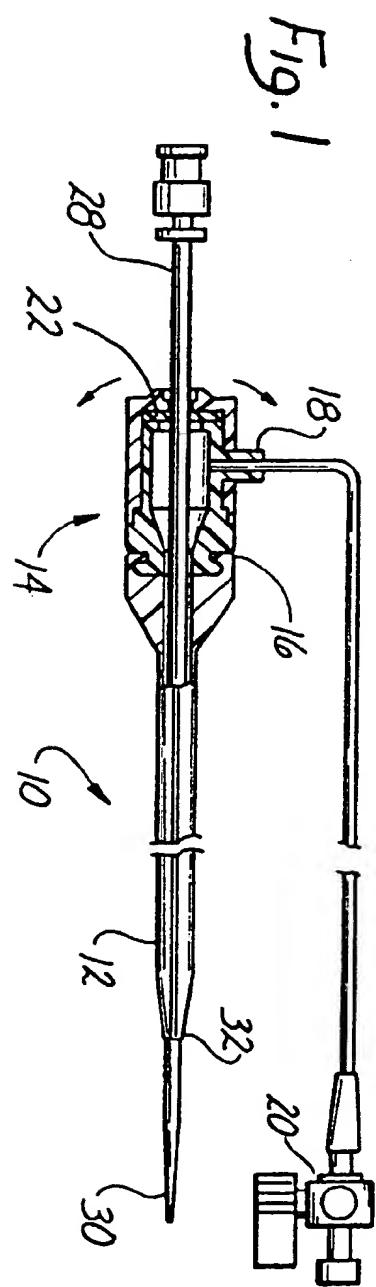
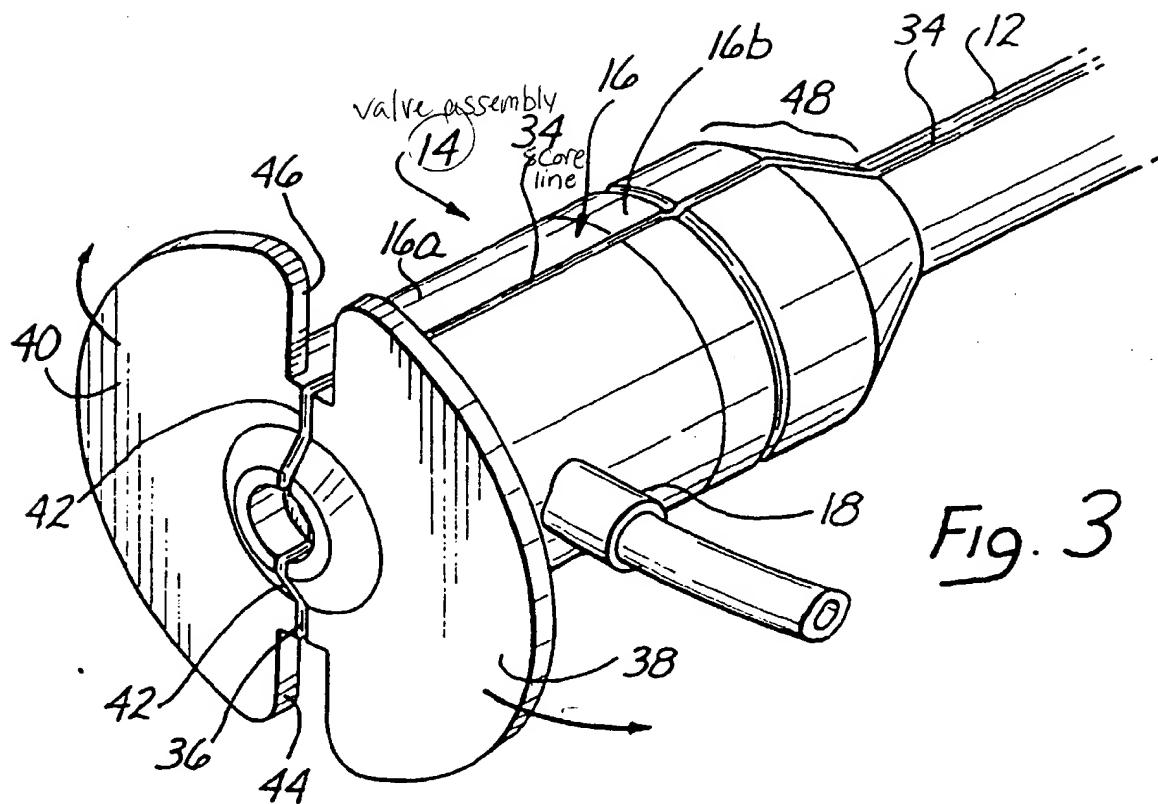


Fig. 1



18 Fig. 3

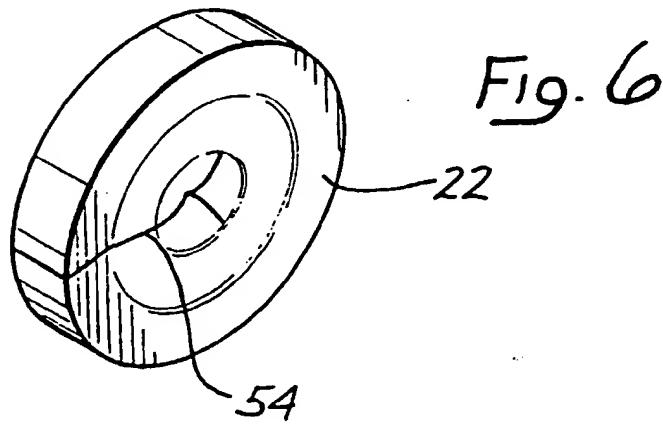


Fig. 6

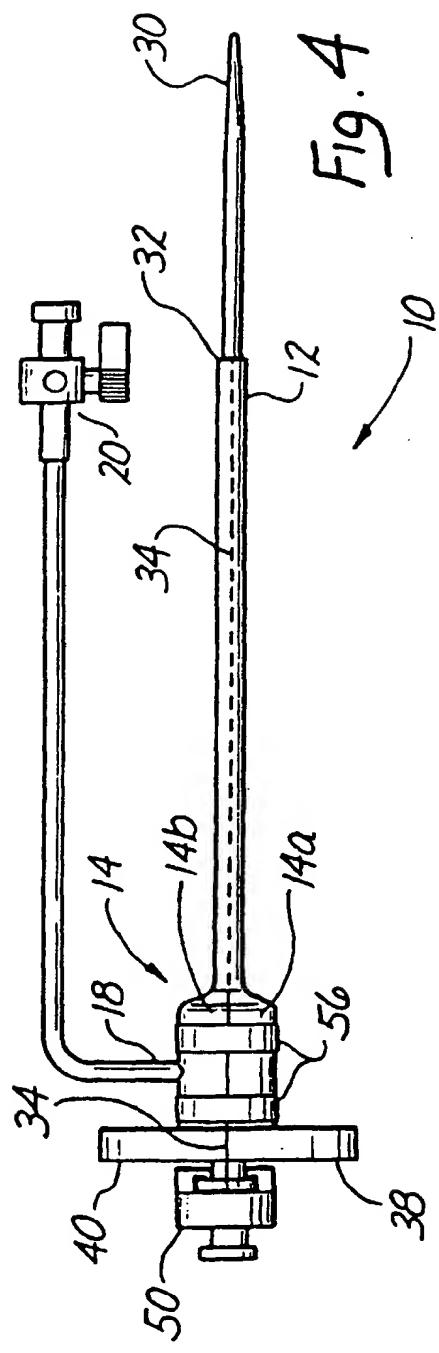


Fig. 4

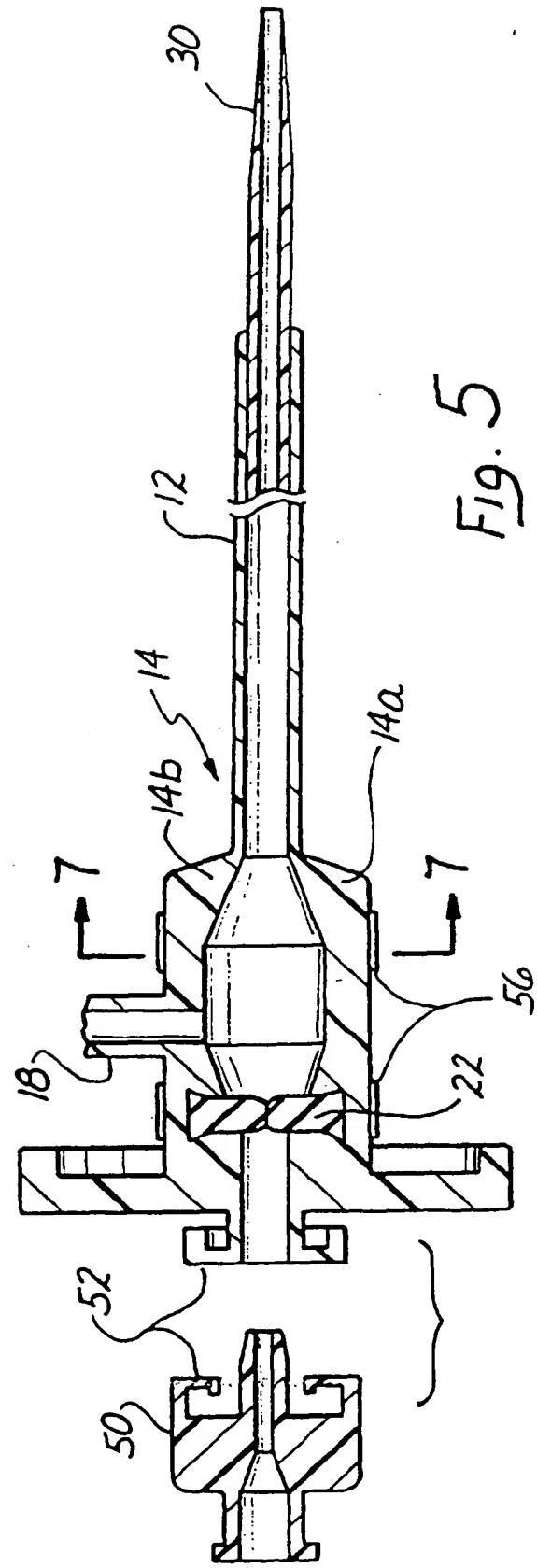
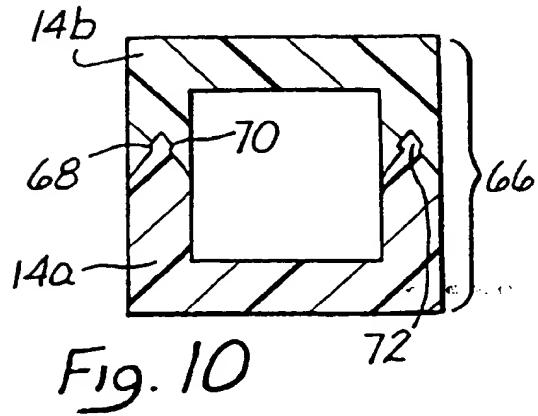
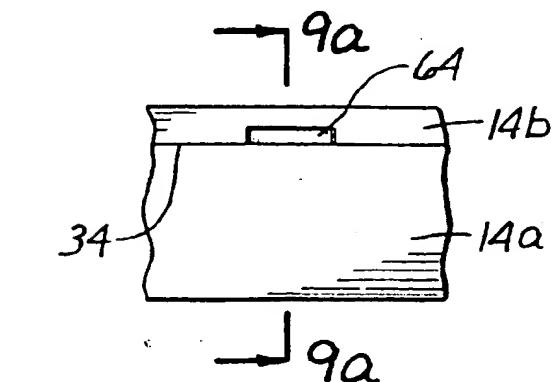
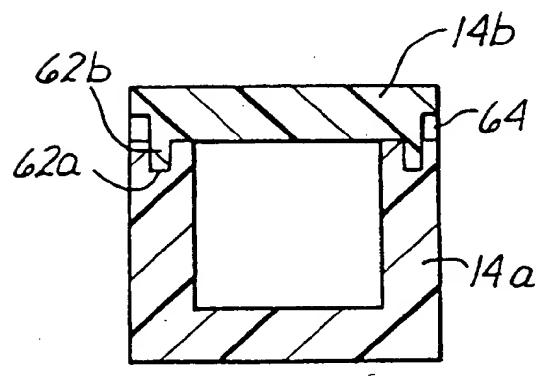
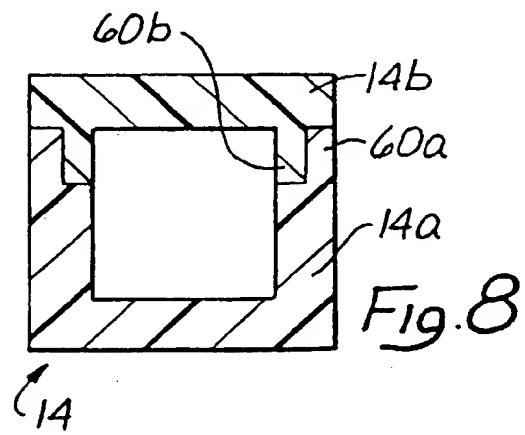
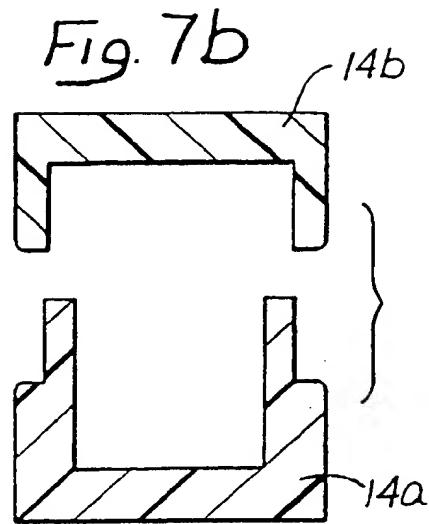
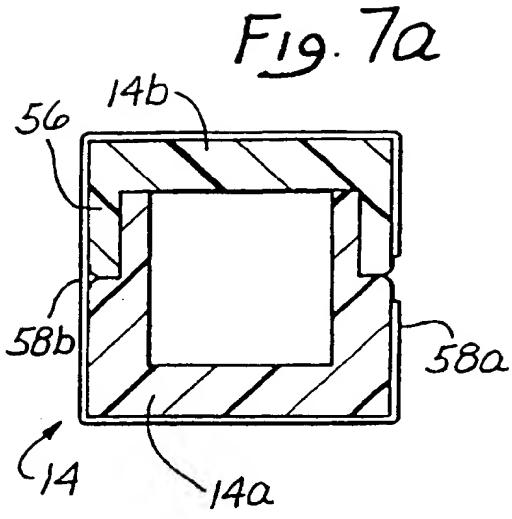


Fig. 5





(19)

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(11)

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(12)

## EUROPEAN PATENT APPLICATION

(88) Date of publication A3:  
29.12.1999 Bulletin 1999/52

(51) Int. Cl.<sup>6</sup>: A61M 25/06

(43) Date of publication A2:  
13.10.1999 Bulletin 1999/41

(21) Application number: 99114016.1

(22) Date of filing: 06.07.1992

(84) Designated Contracting States:  
AT BE CH DE DK ES FR GB GR IT LI LU MC NL  
PT SE

(71) Applicant:  
H.L. MEDICAL INVENTIONS, INC.  
Rancho Palos Verdes, CA 90274 (US)

(30) Priority: 09.07.1991 US 727191  
26.06.1992 US 905045

(72) Inventor: Lee, Hongpyo H.  
Rancho Palos Verdes, CA 90274 (US)

(62) Document number(s) of the earlier application(s) in  
accordance with Art. 76 EPC:  
92919181.5 / 0 593 685

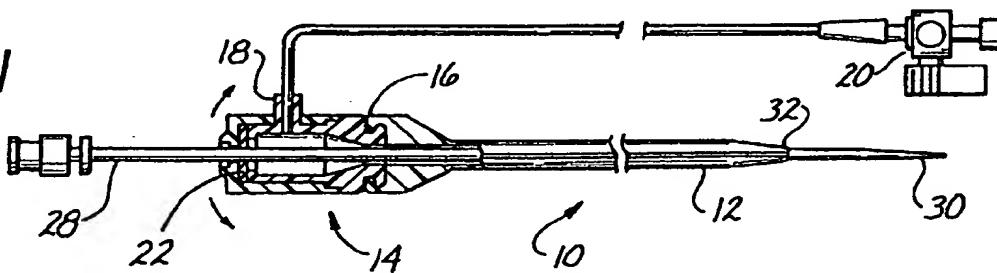
(74) Representative: Hager, Thomas J.  
Hoefer - Schmitz - Weber  
Patentanwälte  
Gabriel-Max-Strasse 29  
D-81545 München (DE)

### (54) Splittable sheath assembly

(57) The invention relates to an apparatus for use for vascular implantation of a lead or catheter comprising a separable introducer sheath (12) adapted for disposition within a body lumen; a separable hemostatic valve (14) coupled to said introducer sheath (12), said hemostatic valve (14) for sealing said lead or catheter within said hemostatic valve (14) to prevent bleeding or introduction of air into said body lumen when said lead or catheter is introduced into said body lumen; characterized in that the apparatus comprises means for per-

mitting removal of said separable introducer sheath (12) and said separable hemostatic valve (14) from said lead or catheter without sliding either said separable introducer sheath (12) or said separable hemostatic valve (14) over said lead or catheter; and means for separating said separable introducer sheath (12) and said separable hemostatic valve (14) in a controlled and predictable manner to permit removal from said lead or catheter.

Fig. 1





## EUROPEAN SEARCH REPORT

Application Number  
EP 99 11 4016

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
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The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	11 November 1999	Clarkson, P	
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			

ANNEX TO THE EUROPEAN SEARCH REPORT  
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